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ORIGINAL ARTICLE

Distal targeting device for long Gamma nail[®]. Monocentric observational study



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KEYWORDS

Fracture;
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Summary

Introduction: Intramedullary nail distal locking screws make it possible to control length and rotation but include an increased risk of radiation exposure. A distal targeting device was recently developed for long Gamma[®] nails (Stryker[®]). The aim of this practical observational study was to evaluate the reliability of this system. Our hypothesis was that the targeting device would be systematically used without conversion or complications.

Materials and methods: All of the long Gamma[®] nails implanted between November 2011 and October 2012 were recorded: 91 nails (59 W/32 M, mean age 73.5 years old) for 68 traumatic fractures, 14 preventive nailings and nine pathological fractures. A junior surgeon performed the procedure in 45 cases and a senior in 46 cases. The number of times the device was used, the difficulties and complications encountered, the duration of fluoroscopy and the dose of radiation were noted. Risk factors were looked for.

Results: The targeting device was used 79 times (the surgeon chose not to use it 11 times, and it was not available in one case). There was a measurement error in one case, therefore 78 nails could be evaluated. Three wrong positions of the distal locking screw occurred. No statistically significant risk factors were identified. Distal locking screw corresponded to 18% of the entire procedure at a radiation dose of 7.44% (this was higher with titanium nails and pathological fractures). Total fluoroscopy time was longer with junior than with senior surgeons but the dose and duration for distal locking were not different.

Discussion: The hypothesis was not confirmed. The device was not systematically used and the risk of complications was not null. No risk factors were identified. The distal locking screw is a difficult step but the use of the targeting device can limit the dose of radiation. This device is effective and allows young surgeons to perform distal locking without increasing the dose of radiation compared to senior surgeons.

Level of evidence: Level IV, cohort study, observational prospective follow-up.

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Introduction

The reference treatment for long bone fractures is intramedullary nailing. The goal is to obtain rapid functional recovery by providing stable fixation for immediate mobilization and early weight bearing [1]. Locked intramedullary nailing controls shortening and rotation of bone fragments [1,2]. Although the proximal cervical screw procedure is normally easy, facilitated by the use of a nail guide, the distal locking screw procedure is more difficult. Besides the possible complications, the patient and surgical team are exposed to perioperative radiation. Numerous methods have been proposed to reduce this risk [3–5] and even to do without radiation and perioperative fluoroscopy all together [4,6–9].

Recently an external distal targeting device was developed for distal locking of the long Gamma® (Stryker®) cervicomedullary nail. We report our practical experience with this device in a single-center observational series. Our study had several goals: to identify prognostic factors and risk factors of failure of the external targeting device, to evaluate the efficacy of the device and the frequency of use, and finally to evaluate its effect on the dose of radiation in relation to the duration of fluoroscopy and the type of fracture, the material of the nail, the surgeon's experience as well as the age, gender and body mass index of the patients. The hypothesis was that the targeting device would be systematically used in a Level I University Hospital traumatology department without conversion and without specific complications.

Materials and methods

Description of the study

This was an observational prospective study performed from November 2011 to October 2012. All long Gamma® nails (Stryker®) implanted during this period were recorded. The use or not of the distal targeting device was noted as well as the type of lesion (traumatic fracture, pathological fracture, preventive nailing), the nail material (titanium or steel), the nail length, the difficulties encountered, the complications observed (misdrilling, fractures, loss of screws), the duration of fluoroscopy for the distal locking screw procedure alone and for the entire intramedullary nailing procedure, the experience of the surgeon (senior: University Medical Professor I, Hospital Practitioner, University Lecturer Hospital Practitioner; junior: resident, Fellow in Medicine), body mass index, age and gender of the patients.

Measurement of the duration of fluoroscopy and the dose of radiation for the distal locking screw began at the moment fluoroscopy was used to prepare the distal locking screw and ended after the final control of the distal locking screw. The duration of fluoroscopy and the dose of radiation were obtained by subtracting the time at the beginning from that of the end of the distal nailing procedure. Direct measurement by placing the device at zero is not possible. Time was expressed in seconds and the dose of radiation in cGy/cm².

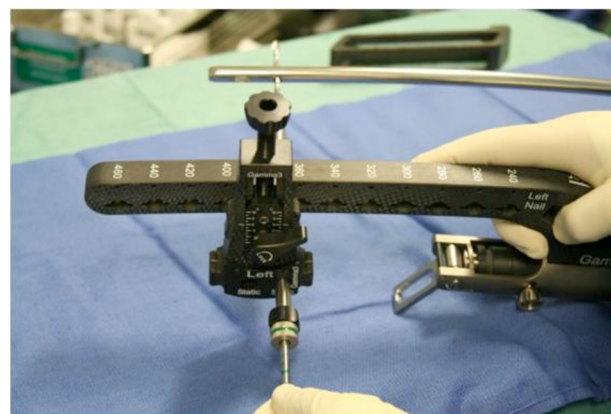


Figure 1 Confirmation of the distal targeting device. Note the position of the drill guide along the mark for the length of the nail (this is a 380 mm nail).

Surgical technique

The usual indications and customary nailing techniques were used, and were not changed for the study. The presence of a total hip prosthesis on the same side was not criteria for exclusion as long as nailing was indicated. A fracture table was always used with the contralateral limb in a gynecological stirrup.

The first step to using the distal targeting device was to confirm the device on the nail (Fig. 1). The drill guide was positioned according to the length of the nail then adjusted using the drill guide sleeve and the 4.2 mm diameter drill tip. The drill tip had to be exactly in the center of the nail hole. Once the nail was in place and the cervicocephalic lag screw was posed, the targeting device was mounted on the traditional nail-guide instrumentation (Fig. 2). With the fluoroscope there was no need to be exactly perpendicular to the nail because unlike the classic free-hand technique, a perfectly aligned image of the sleeve on the distal hole and the image of perfectly round holes were not necessary. A view at a 30° angle of the nail is possible. This angle gives the surgeon working space, facilitating the procedure and limiting the risk of infection (Fig. 3). The nail and the drill sleeves were brought together under fluoroscopic control.

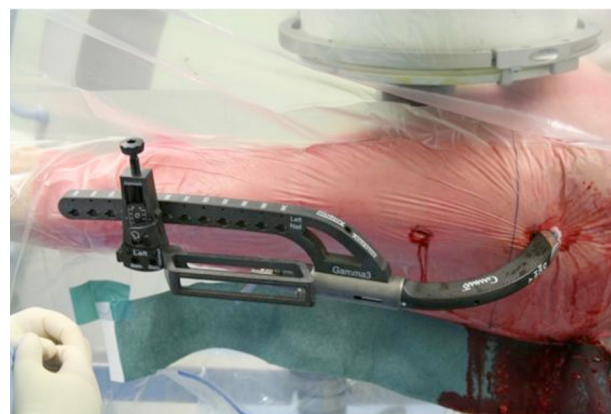


Figure 2 Placement of the external distal targeting device on the classic proximal nail device of the Gamma Long Nail®.

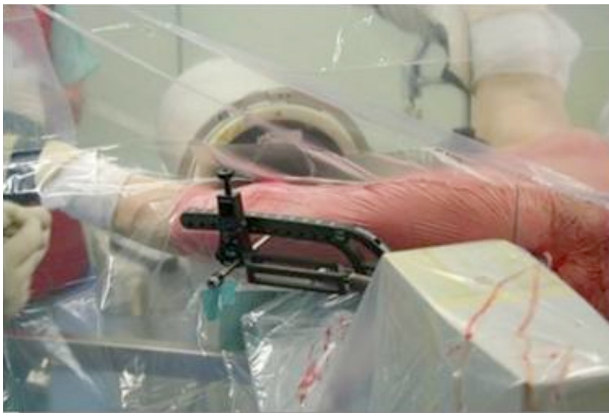


Figure 3 Perioperative view of the angle of the fluoroscope in relation to the leg, a surgical field is created.

This was facilitated by using a targeting guide (Fig. 4) and by being able to adapt the drill guide vertically (Fig. 5). There are two steps to this procedure:

- the nail and the reference lines of the targeting guide were lined up by fluoroscopy until they were parallel to each other (Fig. 4b);

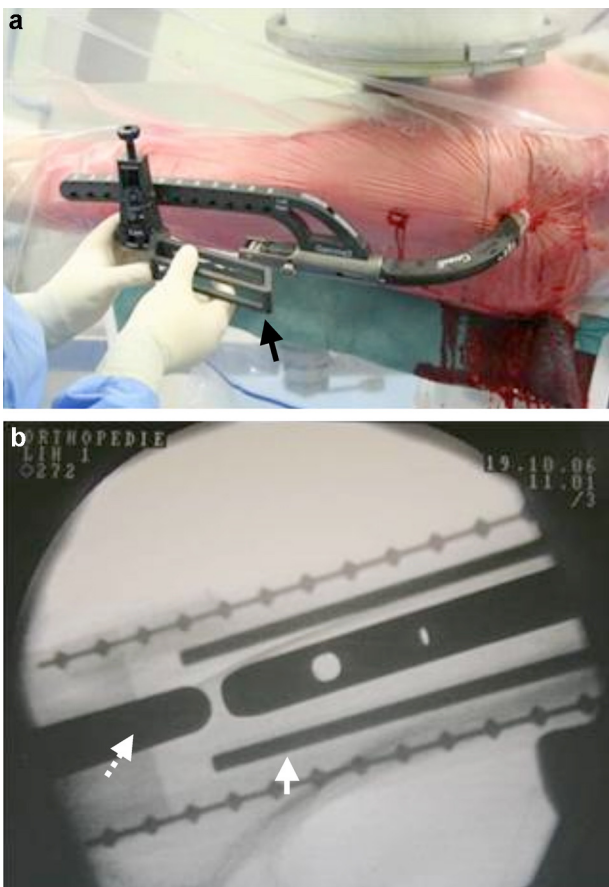


Figure 4 Distal targeting device: a: targeting guide in place (black arrow); b: fluoroscopy with the alignment of the drill sleeve (white dotted arrow) and the reference line of the targeting guide (solid white arrow).



Figure 5 Possible adaptation and sagittal correction of the drill guide with 14 mm leeway in front or behind the nail.

- the nail and the drill sleeve were lined up.

Coronal plane deformity and torsion have very little influence on the distal locking screw and the use of the targeting device, while sagittal plane deformity affects the targeting angle [10]. Correction was therefore necessary and possible thanks to the drill guide wrench with possible correction of 14 mm downwards and upwards (Fig. 5). Performing the distal locking screw procedure in two steps by leaving a drill bit in the distal hole provided additional stability to the system by creating a frame (nail – nail device – targeting device – drill bit).

Statistical analysis

Group comparisons for qualitative variables were performed with the Fischer test, and group comparisons for quantitative variables by the Wilcoxon test. $P < 0.05$ was considered to be significant.

Results

The series

The series included 91 long Gamma® nails in 91 patients (59 women/32 men), mean age 73.5 years old (median 78; 23–100), with a mean body mass index of 24.7 kg/m² (median 24; 14.8–39). The left side was involved in 42 cases and the right side in 49. There were 68 traumatic fractures, 14 preventive nailings and nine pathological fractures. A senior surgeon performed 46 of the operations and a junior 45. Preoperative embolisation was not performed in any of the malignant lesions. A titanium nail was used 29 times, mainly for pathological fractures or preventive nailing ($n = 21$) and a steel nail 62. The length of the nails varied from 320–460 mm (median 380 mm). Two distal locking screws were systematically used.

Table 1 Main results of the groups for fluoroscopic time (seconds) and radiation dose (in mGy/cm²).

	Fluoroscopy time (s)	Dose (mGy/cm ²)	Number of cases
Total nailing procedure (the entire series)	106.2 (36–330) Med 83	4573.9 (1000–11,983.8) Med 3802.8	91
Distal locking screw with the targeting guide (the entire distal targeting device series)	17.5 (4–104) Med 13.5	241.3 (40–1572) Med 174	78
Distal locking screw with the distal targeting device in the “fracture” group	16.3 (4–104) Med 12	247.8 (40–1572) Med 180	57
Distal locking screw with the distal targeting device in the “pathological” group (fracture + preventive)	20.6 (6–62) Med 20	223.8 (100–810) Med 160	21
Distal locking screw with the distal targeting device by the “senior” group	17.6 (5–62) Med 13	229.3 (63–810) Med 160	41
Distal locking screw with the distal targeting device by the “junior” group	17.35 (4–104) Med 15	257.7 (40–1572) Med 180	37
Distal locking screw with the distal targeting guide in the “titanium” group	18.74 (6–62) Med 15	208.6 (63–810) Med 160	27
Distal locking screw with the distal targeting device in the “steel nail” group	16.8 (4–104) Med 12	258.6 (40–1572) Med 180	51

Results

The distal targeting device was used 79 times. The surgeon chose not to use it 11 times and in one case it was not available. In one case measurement of time and radiation dose during distal locking with the targeting device was not performed. Therefore, 78 cases of the distal locking screw procedure were evaluated (78/91) in 57 fractures, 14 preventive nailings and seven pathological fractures. Fluoroscopy lasted a mean 17.5 seconds (median 13.5; 4–104) for the distal locking screw procedure with the targeting device and the mean dose of radiation was 241.3 mGy/cm² (median 174; 40–1572). Distal locking time corresponded to 18% (median 14.8%; 3.8–57.4) of the entire procedure and the radiation dose to 7.44% (median 4.75; 1–63.1) of the total dose. Table 1 shows the main results of the “groups”.

Three misdrillings were observed: in one pathological fracture and two traumatic fractures, by two junior surgeons and one senior, using two steel nails.

No statistically significant risk factors were found for the use of the targeting device (length of the nail, material, type of fracture, experience of the surgeon, BMI, gender or age). The percentage of time and the dose of radiation for the distal locking screw procedure compared to the entire procedure were greater with titanium nails (time = $P < 0.05$ and dose = $P < 0.04$) and pathological fractures (time = $P < 0.004$ and dose = $P < 0.02$). However, the

duration of fluoroscopy and the dose of radiation for the entire procedure were shorter for pathological fractures (time = $P < 0.03$ and dose = $P < 0.005$) and for preventive nailing (time = $P < 0.02$ and dose = $P < 0.0002$). Total fluoroscopy time for the entire procedure was longer for junior surgeons than for senior ($P = 0.02$), while the dose of radiation was identical. On the other hand, the duration and dose of radiation of distal locking alone were not different between junior and senior surgeons.

Discussion

The main goals of the distal targeting device for distal nailing are, firstly, to facilitate and obtain a successful distal locking screw procedure and, secondly, to reduce or even eliminate perioperative radiation. Although the specifications of these devices are theoretically simple, in practice they are not. Indeed the intramedullary nail is deformed after it is inserted into the medullary canal. This is dependent upon the geometry of the nail and the surgical technique. Non-slotted nails are less flexible and less deformable than slotted nails and therefore undergo less torsional and rotational loading [11,12]. Although the shape of reamed nails is adapted by reaming of the medullary canal, they also undergo deformation but less than non-reamed nails, which absorb significant loads [13,14]. However, certain loading and deformation can be considered negligible. Femoral nails

Table 2 Results in the literature on the time and radiation doses of distal locking screw of femoral nails.

Series	Fluoroscopy time	Distal locking screw time (min)	Radiation dose distal locking screw (mGy/cm ²)
<i>Free-hand</i>			
Sanders et al. [21]	3.44 min		
Coetzee and Merwe [22]	4.6 min		
Uruc et al. [23]	18.29 s	18.35	
Krettek et al. [24]	37 s	4.8	
<i>Mechanical guide</i>			
Anastopoulos et al. [5]	1.35 s	6.6	1.9
Arlettaz et al. [6]	55 s	31	
Krettek et al. [24]	0 s	6.6	

are relatively stable during torsion and deformation mainly occurs on the sagittal plane [15,16]. Moor et al. [10] have shown that frontal deformation is also negligible in femoral nails. These results emphasize the practical difficulty of determining the specifications for this device. Guides must be adapted to different nail deformations to obtain high quality nailing and to integrate correction of the sagittal component of the nail after implantation, which may be significant and go beyond the ability of the device to correspond to the level of nail deformation [5].

Numerous techniques have been developed to obtain successful distal locking, from mechanical assistance with specific devices to computer-assisted navigation [3–9]. Certain authors have proposed very simple means such as using a nail of the same length as a reference (nail over nail technique) [17] or taking a direct anterior femoral approach by a cortical window [18]. Specific distal devices have been shown to provide high quality femoral [5,6] and tibial distal locking [19]. They have also been shown to effectively and significantly reduce the time and dose of radiation compared to classic free-hand distal locking [18,20].

Recently a distal targeting device for the Gamma® long nail (Stryker®) was developed. To our knowledge there have been no studies published on this device.

Our hypothesis was not confirmed because the device was not systematically used ($n=79/91$, 87%), failure occurred ($n=3$), but no risk factors were identified. The failures ($n=3$) emphasize the existence of a learning curve, and were not associated with an indication, a material or the surgeon's experience. It is interesting to note that total nailing time was longer ($P=0.02$) for junior surgeons, although there was no difference (time and dose) in the distal locking screw procedure when the targeting device was used. This proves that the use of this device makes it possible to eliminate differences in relation to the surgeon's experience observed for the entire procedure, by reducing nailing time in this part of the procedure. Moreover, distal locking was proportionally longer with more radiation for titanium nails and pathological fractures, although these factors were not identified as a statistical risk factor for the use of the targeting device. It should be noted that the entire preventive nailing procedure used less radiation but that the distal locking screw procedure represented a large proportion of the total radiation for this nailing procedure in this indication.

Our study has certain weaknesses and limitations. There was no control group and the study was designed to evaluate complications and the limits of this device rather than compare it to other techniques. Table 2 compares the results in the literature on the duration of the distal locking screw procedure and fluoroscopy and the dose of radiation for femoral distal locking with a classic free-hand technique or with a targeting device.

Our study did not identify any risk factors. The material, type of fracture, experience of the surgeon, length of the nail, body mass index, gender and age did not influence the use or results of this device. There are very few clinical or anatomical studies that have focused upon the risk factors or limits of use of these targeting devices. Pardiwala et al. [12] showed that obesity was a limitation as well as a too distal position of the femoral nail, in particular when the tip of the nail descends below the proximal pole of the patella. Steripoulos et al. [25] also considered obesity to be critical. Reaming of more than 1.5 mm of the diameter of the nail has been considered by some to be a limitation because there is a risk of creating too much deformation load [12]. Anastopoulos et al. [5] had five failures including three that were explained by extensive nail deformation. Analysis of these cases suggests the following risk factors: the importance of the entry point (too lateral and posterior), fractures of the distal third of the femur and whether the neck is intact. Although misdrilling occurred, these did not result in complications or have any clinical effects [5,14]. Finally it has been shown that surgery is not longer with these devices, and that the surgical procedure is not changed, on the contrary, nailing is more precise [5,15,24].

Conclusion

The results of this study showed that this targeting device is effective and in particular allows junior surgeons to perform the distal locking screw procedure without increasing the dose of radiation compared to senior surgeons, thus removing the effect of experience. No risk factors influencing results were identified. The goal of simplifying the distal locking screw procedure was achieved, but there were still some complications. However, the hypothesis was not confirmed because there were complications and the targeting device was not systematically used in daily practice.

Disclosure of interest

Dillmann Gauthier, Czeka Jarek, Brinkert David, Schenck Benoît, DiMarco Antonio: declare that they have no conflicts of interest concerning this article.

Ehlinger Matthieu, Adam Philippe: consultant Synthes®.

Taglang Gilbert: educational consultant Stryker®.

Bonnomet François: educational consultant Zimmer®.

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